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 Serial No.: 09/435,249
 Applicant: Schneider, Jay S.
 Filing Date: November 5, 1999
 Art No. 1635
 Examiner Schmidt, M.

Information Disclosure
 Statement by Applicant
 (use several Sheets if necessary)

U.S. PATENT DOCUMENTS

| Exmr Initial | Patent Number | Issue Date | Patentee | Class | Sub- Class | Filing Date If Appropriate |
|-----------------|---------------|---------------|--------------------|-------|---------------|----------------------------------|
| mmg | 5,929,042 | July 27, 1999 | Troy, et al. | 514 | 44 | |
| mmg | 5,929,226 | July 27, 1999 | Padmapriya, et al. | 536 | 25.3 | |

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

| Exmr Initial | Document Number | Publn Date | Country or Patent Office | Class | Sub- Class | Translation? Yes No |
|-----------------|--------------------|---------------|-----------------------------|-------|---------------|------------------------|
| | | | | | | |

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Place of Publication**)

| | |
|-----|---|
| mmg | STULL, R.A., et al., "Predicting Antisense Oligonucleotide Inhibitory Efficacy: A Computational Approach Using Histograms and Thermodynamic Indices", <u>Nucleic Acids Research</u> , Vol. 20, No. 13, pp. 3501-3508, 1992. |
| | STULL, R.A., et al., "An in vitro Messenger RNA Binding Assay as a Tool for Identifying Hybridization-competent Antisense Oligonucleotides", <u>Antisense & Nucleic Acid Drug Development</u> , Vol. 6, pp. 221-228, 1996. |
| | BACON, Thomas A. and WICKSTROM, E., "Walking Along Human c-myc mRNA with Antisense Oligodeoxynucleotides: Maximum Efficacy at the 5' Cap Region", <u>Oncogene Research</u> , Vol. 6, pp. 13-19, 1991. |
| | BENNETT, C.F., et al., "Pharmacology of Antisense Therapeutic Agents". <u>Methods in Molecular Medicine: Antisense Therapeutics</u> (Agrawal, S, ed.), Humana Press, Totowa, New Jersey, pp. 13-46, 1996. |
| | AKHTAR, S. and AGRAWAL, S., "In vivo Studies with Antisense Oligonucleotides", <u>Trends in Pharmacol. Sciences</u> , Vol. 18, pp. 12-18, 1997. |
| | BRYSCH, et al., "Anisense-Mediated Inhibition of Protein Synthesis of Protein Synthesis", <u>Methods in Molecular Medicine: Antisense Therapeutics</u> , (Agrawal, S., ed.), Humana Press, Totowa, New Jersey, pp. 166 and 175-176, 1996. |
| | COSSUM, P.A., et al., "Disposition of the C-Labeled Phosphorothioate Oligonucleotide ISIS 2105 after Intravenous Administration to Rats", <u>J. Pharmacol. Exp. Ther.</u> , Vol. 267, No. 3, pp. 1181-1190, 1993. |
| | COSSUM, P.A., et al., "Pharmacokinetics of a C-Labeled Phosphorothioate Oligonucleotide, ISIS 2105, after Intradermal Administration to Rats", <u>J. Pharmacol. Exp. Ther.</u> , Vol. 269, No. 1, pp. 89-94, 1994. |
| | AGRAWAL, S., et al., "Pharmacokinetics, Biodistribution, and Stability of Oligodeoxynucleotide Phosphorothioates in Mice", <u>Proc. Natl. Acad. Sci.</u> , Vol. 88, pp. 7595-7599, 1991. |
| ✓ | TEMSAMANI, J., et al., "Pharmacokinetics, Biodistribution, and Stability of Capped Oligodeoxynucleotide Phosphorothioates in Mice", <u>Antisense Res. Dev.</u> , Vol. 3: 277-284, 1993. |

Examiner

Date Considered

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

(Form PTO - 2)

* Use publication date indicated on the patent or published application. 37 CFR 1.98(b).

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|-----------------|---------------|---------------|----------|-------|---------------|----------------------------------|
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|-----------------|--------------------|---------------|-----------------------------|-------|---------------|------------------------|
| | | | | | | |

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Place of Publication**)

| | |
|------------------|---|
| mm | SANDS, H., et al., "Biodistribution and Metabolism of Internally H-Labeled Oligonucleotides. I. Comparison of a Phosphodiester and a Phosphorothioate", <u>Mol. Pharmacol</u> , Vol. 45, pp. 932-943, 1994. |
| | SAIJO, Y., et al., "Pharmacokinetics, Tissue Distribution, and Stability of Antisense Oligodeoxynucleotide Phosphorothioate ISIS 3466 in Mice", <u>Oncol. Res.</u> , Vol. 6:243-249, 1994. |
| | DeDIESBACH, P. et al., "Identification, Purification and Partial Characterization of an Oligonucleotide Receptor in Membranes of HepG2 Cells", |
| | LOKE, S.L. et al., "Characterization of Oligonucleotide Transport into Living Cells", <u>Proc. Natl. Acad. Sci. USA</u> , Vol. 86, pp. 3474-3478, May 1989. |
| | HANSS, B. et al., "Identification and Characterization of a Cell Membrane Nucleic Acid Channel", <u>Proc. Natl. Acad. Sci. USA</u> , Vol. 95, pp. 1921-1926, February, 1998. |
| | BENIMETSKAYA, L. et al., "Mac-1 (CD11b/CD18) is an Oligodeoxynucleotide-binding Protein", <u>Nature Medicine</u> , Vol. 3, No. 4, pp. 414-420, 1997. |
| | YAKUBOV, Leonid A. et al., "Mechanism of Oligonucleotide Uptake by Cells: Involvement of Specific Receptors?", <u>Proc. Natl. Acad. Sci. USA</u> , Vol. 86:6454-6458, Sept., 1989. |
| | POLITZ, Joan C. et al., "Intranuclear Diffusion and Hybridization State of Oligonucleotides Measured by Fluorescence Correlation Spectroscopy in Living Cells", <u>Proc. Natl. Acad. Sci. USA</u> , Vol. 95, pp. 6043-6048, May 1998. |
| | POLITZ, Joan C., et al., "Characterization of Hybridization Between Synthetic Oligodeoxynucleotides and RNA in Living Cells", <u>Nucleic Acids Research</u> , Vol. 23, No. 24, 1995. |
| | WHITESELL, Luke, et al., "Stability, Clearance, and Disposition of Intraventricularly Administered Oligodeoxynucleotides: Implications for Therapeutic Application Within the Central Nervous System", <u>Proc. Natl. Acad. Sci. USA</u> , Vol. 90:4665-4669, May 1993. |
| | International Search Report mailed 22 February 2000 from corresponding International Application No. PCT/US99/26128, filed 05 November 1999. |
| Examiner | Date Considered |
| <i>M Schmidt</i> | <i>1/1/01</i> |

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